From: OCSPPNews [OCSPPNews@epa.gov]

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To: Blair, Susanna [Blair.Susanna@epa.gov]; Carlisle, Sharon [Carlisle.Sharon@epa.gov]; Dennis, Allison

[Dennis.Allison@epa.gov]; Diaz, Catherine [Diaz.Catherine@epa.gov]; Drinkard, Andrea [Drinkard.Andrea@epa.gov];

Dunton, Cheryl [Dunton.Cheryl@epa.gov]; Freedhoff, Michal [Freedhoff.Michal@epa.gov]; Garcia, Beth [garcia.beth@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]; Hanley, Mary [Hanley.Mary@epa.gov]; Hartman, Mark [Hartman.Mark@epa.gov]; Harwood, Laura [Harwood.Laura@epa.gov]; Hauff, Amanda

[Hauff.Amanda@epa.gov]; Henry, Tala [Henry.Tala@epa.gov]; Hughes, Hayley [hughes.hayley@epa.gov]; Kaiser,

Sven-Erik [Kaiser.Sven-Erik@epa.gov]; Keigwin, Richard [Keigwin.Richard@epa.gov]; Kochis, Daniel

[Kochis.daniel@epa.gov]; Kovner, Karissa [Kovner.Karissa@epa.gov]; Kragie, Sheila Xiah [kragie.sheila@epa.gov];

Kramer, George [Kramer.George@epa.gov]; Labbe, Ken [Labbe.Ken@epa.gov]; Layne, Arnold

[Layne.Arnold@epa.gov]; Li, Jake [Li.Jake@epa.gov]; Lourie, Noah [Lourie.Noah@epa.gov]; Messina, Edward

[Messina.Edward@epa.gov]; Nguyen, Khanh [Nguyen.Khanh@epa.gov]; OPP Branch Chiefs

[OPP_Branch_Chiefs@epa.gov]; OPP Deputy & Associate Directors [OPP_Deputy_&_Associate_Directors@epa.gov];

OPP Division Directors [OPP_Division_Directors@epa.gov]; OPP IO [OPP_IO@epa.gov]; OPPT Managers

[OPPT_Managers@epa.gov]; OPS CSID CB [OPS_CSID_CB@epa.gov]; Parsons, Doug [Parsons.Douglas@epa.gov]; Picone, Kaitlin [Picone.Kaitlin@epa.gov]; Pierce, Alison [Pierce.Alison@epa.gov]; Pinto, Ana [Pinto.Ana@epa.gov]; Richmond, Jonah [Richmond.Jonah@epa.gov]; Romanovsky, Anna [Romanovsky.Anna@epa.gov]; Romer, Jennie [Romer.Jennie@epa.gov]; Scheifele, Hans [Scheifele.Hans@epa.gov]; Schmit, Ryan [schmit.ryan@epa.gov]; Siciliano,

CarolAnn [Siciliano.CarolAnn@epa.gov]; Smith, Carolyn [smith.carolyn@epa.gov]; Sullivan, Melissa

[sullivan.melissa@epa.gov]; Tyler, Tom [Tyler.Tom@epa.gov]; Varnado, Miriam [Varnado.Miriam@epa.gov]; Vendinello, Lynn [Vendinello, Lynn@epa.gov]; Vernon, Jennifer [Vernon.Jennifer@epa.gov]; Weiner, Janet

[Weiner.Janet@epa.gov]; Zapata, Cesar [Zapata.Cesar@epa.gov]

Subject: OCSPP News for December 30, 2021

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'Buckle Up' for PFAS Regulation, Litigation in 2022, Lawyers Say

Pat Rizzuto, Bloomberg Law

https://news.bloomberglaw.com/environment-and-energy/buckle-up-for-pfas-regulation-litigation-in-2022-lawyers-say?utm_source=twitter&utm_medium=ehsdesk&utm_campaign=1D29FA2C-6977-11EC-824D-8CB44F017A06

Industries are advised to brace for more federal moves next year to reduce and control "forever chemicals," including plans by the EPA to propose water and waste regulations for two per- and polyfluoroalkyl substances, or PFAS.

The Environmental Protection Agency also will be gathering data on other types of PFAS in 2022 that could shape future regulations. Meanwhile, states are expected to take steps to eliminate uses of PFAS and the volume of them that goes up smokestacks, into water, and onto land, attorneys say.

"There will be more change on the regulatory front than we have had in a long time, and fairly significant regulatory change," said Ashley Peck, a partner specializing in water issues at Holland and Hart LLP. "My advice for water utilities is to buckle up and pay attention."

Other industries including many different types of manufacturers and companies that import products ranging from cables to computers to cars also could be pulled into the regulations the EPA is developing.

And to move the ball quicker, environmental and consumer groups plan to target retailers asking them to stop selling cosmetics, textiles, and some other products made with PFAS.

'So Much Litigation'

EPA's PFAS Strategic Roadmap details dozens of regulatory, research, and technological commitments it will be taking in 2022 and beyond to address what it described as "an urgent public health and environmental issue facing communities across the United States."

Some of the chemicals, which are used to make thousands of industrial and consumer products, can linger for decades in the environment and people's bodies.

Perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) will be the target of EPA rules in 2022, including a proposed rule in spring, designating them as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act, known as the Superfund program.

That designation, if finalized, would require companies and federal facilities to report releases of PFOA and PFOS above a certain threshold, trigger cleanups, and require responsible parties to pay for cleanup.

The possibility already is affecting corporate discussions about buying and selling property, said Michael Blumenthal, an attorney with McGlinchey Stafford PLLC and former environmental prosecutor for Ohio. Purchasers are investigating whether a company or property they might buy has used or disposed of PFAS before deciding whether to buy them, he said.

Some EPA regional offices also are suggesting that parties responsible for Superfund cleanups consider getting ahead of the curve and finding out whether PFAS are contaminants they'll have to deal with, Blumenthal said.

For example, he's working with a group of companies that are preparing a remediation plan for an East Coast Superfund site. They're discussing whether to examine their own corporate history with PFAS and test the site for the chemicals, he said. That could be more expensive in the short run but cheaper than redoing the plan or even reopening a cleaned up site in the long run, he said.

If PFOA and PFOS are deemed hazardous waste, Blumenthal said closed Superfund sites could be reopened and "landfills will have no choice but to go after industries that contributed the chemicals," to their site.

"There will be so much litigation," he said.

In addition to Superfund, the EPA will be working in 2022 on a proposal to designate PFOA, PFOS, perfluorobutane sulfonic acid (PFBS), and the GenX chemicals—officially called hexafluoropropylene oxide (HFPO) dimer acid along with its ammonium salt—as hazardous wastes regulated under the Resource Conservation and Recovery Act.

That rule, which the EPA plans to propose in 2023, would set disposal requirements for the chemicals and wastes containing them. RCRA rules, however, don't trigger the extensive litigation that Superfund regulations do.

'Difficult' Water Situations Meanwhile, attorneys will watch to see [...]

PFAS destruction technologies are starting to emerge

Cheryl Hogue, Chemical & Engineering News https://cen.acs.org/environment/persistent-pollutants/PFAS-destruction-technologies-starting-emerge/100/i1

Communities across the US are desperate to rid their environments of toxic per- and polyfluoroalkyl substances (PFAS), especially when these chemicals are in their drinking water. But even when PFAS are successfully filtered out of water, disposing of the extracted material remains a challenge. Now Congress is starting to examine technologies to destroy these widely used synthetic chemicals.

Strengthened by carbon-fluorine bonds rarely found in nature, PFAS are used in applications such as cosmetics, water- and fire-resistant clothing, and aerospace equipment. But their durability also makes them environmentally persistent. Some forms of PFAS are toxic and linked to health problems including immune system dysfunction, endocrine disruption, and cancer. In hundreds of communities nationwide, water supplies are tainted with hazardous PFAS from manufacturing facilities and from the use of firefighting foams at commercial airports and military airfields.

At a Dec. 7 hearing held jointly by two subcommittees of the US House of Representatives Committee on Science, Space, and Technology, lawmakers learned about one emerging approach to PFAS destruction, supercritical water oxidation. Battelle, a nonprofit research and development organization that does contract work mainly for the US government, presented its work developing the technology.

Battelle's PFAS Annihilator technology relies on supercritical water plus an oxidizer to break the carbon-fluorine bonds in these persistent compounds, Amy Dindal, the organization's director of environmental research and development, said at the hearing.

The technology uses water above its critical point of 374 °C and 22 MPa and breaks PFAS into smaller molecules including hydrofluoric acid. Sodium hydroxide is added to neutralize the acid and form sodium fluoride, the organization says in an email. Sodium sulfate also forms if the PFAS contained sulfonate functional groups. A separator removes some of the salts, the rest are released at low levels in treated water, Battelle says.

Battelle's website says its technology works on PFAS regardless of their sizes or specific structures and lowers PFAS concentrations in water to nondetectable levels within seconds.

In a recently published case study, researchers from the US Environmental Protection Agency examined

supercritical water oxidation technology from Battelle, 374Water of Durham, North Carolina, and Denmark's Aquarden Technologies. The researchers specifically looked at the potential of the technologies to destroy PFAS in water-diluted firefighting foams containing perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) (J. Environ. Eng. 2021, DOI: 10.1061/(ASCE)EE.1943-7870.0001957). They found that supercritical water oxidation technologies could destroy more than 99% of the PFAS run through them. The EPA team says more information is needed on operation and maintenance costs of supercritical water oxidation and on the technology's potential for emitting PFAS into air or creating hazardous by-products.

While the congressional hearing gave attention only to supercritical water oxidation, this method is just one of the processes researchers are developing for PFAS destruction.

"Thermal technologies in general are one of the most promising approaches for actually achieving PFAS destruction," Timothy J. Strathmann, a professor of civil and environmental engineering at the Colorado School of Mines, tells C&EN. Thermal technologies include incineration and pyrolysis as well as supercritical or subcritical water with oxidation, he says.

Strathmann's group is working on subcritical hydrothermal technology that uses an alkali, like sodium hydroxide, as a reactant. The team, like many research groups, is also working on other approaches.

At the House hearing, Battelle's Dindal told lawmakers that its PFAS Annihilator is an "economically viable solution."

Battelle has been [...]

US EPA grants North Carolina PFAS testing petition, without new efforts

Julia John, Chemical Watch

https://chemicalwatch.com/397601/us-epa-grants-north-carolina-pfas-testing-petition-without-new-efforts

The US EPA has granted an NGO citizens' petition to compel testing on the health and ecological effects of dozens of per- and polyfluoroalkyl substances (PFASs) – without communicating any intentions to expand already-unfolding work.

The petitioners claim the agency is deploying a "smoke and mirrors" tactic to conceal its lack of action on the compounds found near a Chemours plant in Fayetteville, North Carolina. The groups – the Center for Environmental Health (CEH), Cape Fear River Watch, Clean Cape Fear, Democracy Green, Toxic Free NC and NC Black Alliance – say they will challenge the decision to not immediately meet their demands, possibly by resuming litigation over their request.

The agency announced on 28 December it would grant the previously denied petition and "exercise its TSCA authorities to compel development of information on PFASs". The request, originally filed in autumn 2020, aimed to force Chemours to research 54 substances it allegedly emitted.

But the EPA did not make any new commitments when granting the petition.

In a letter to the organisations' counsel, Robert Sussman, assistant administrator Michal Freedhoff outlined how the agency's broader iterative PFAS testing scheme, released in October, overlaps with their demands. According to her, the first set of TSCA test orders will require manufacturers to generate toxicity information on seven compounds named in the request, and will produce information applicable to 30 of them.

Nine others may at some point undergo assessment through the initiative, and the agency has sound data on several of the last 15, she said. "The EPA is conducting more in-depth analyses of the sufficiency of the existing data, which will inform later phases of testing."

The initial test orders will include animal experiments focused on human toxicity issues the nonprofits listed, and future testing tiers detailed in the orders may incorporate additional endpoints like cancer, based on initial findings.

Aligning with the most recent science, the agency will rely on single substance toxicities to deduce PFAS mixture toxicities, Dr Freedhoff said. It is also looking into building on its involvement in ongoing investigations into North Carolina PFAS exposures.

However, regarding methods for detecting the chemicals in the environment, Dr Freedhoff noted that the agency thinks it inappropriate to mandate analytical standards with the initial test orders.

Advocates dismayed

According to the petitioners, the EPA "missed the entire purpose of the petition – to address the public health needs of a severely contaminated community".

The agency's process of extrapolating out to 30 compounds is "highly theoretical and unproven", and contradicts expert guidance that analyses should directly examine those substances potentially jeopardising human health, the organisations said. And the agency did not commit to certain critical studies related to epidemiology, cancer and PFAS mixtures tainting drinking water and people's blood, they added.

With a meaningful response to their demands, the groups said, "the data EPA could have gained – at the polluters' expense – would support their national PFAS strategy and provide answers to communities across the US and the world."

Former senior EPA official Mr Sussman told Chemical Watch the agency "is putting the financial interests of industry ahead of protection of devastated front-line communities". There is "a very strong legal and scientific basis" for mandating the research, he said, and "it is tragic that EPA is failing to use the authority it has."

Connor Kippe, Toxic Free NC's policy advocate, added that "North Carolina communities deserve to understand the unique health impacts of decades of exposure to 'forever chemical' contamination."

Dana Sargent, executive director of Cape Fear River Watch, said "as the director of an environmental nonprofit who believed in and trusted the folks of this EPA to do the right thing, I am furious."

EPA Eyes Broader Range Of Health Effects In 'Part 2' Asbestos Evaluation

Maria Hegstad, Inside EPA

https://insideepa.com/daily-news/epa-eyes-broader-range-health-effects-part-2-asbestos-evaluation?utm_source=dlvr.it&utm_medium=twitter

EPA's proposed scope for the "part 2" TSCA evaluation of asbestos covers a longer list of possible human effects from exposure than the "part 1" review of risks from ongoing chrysotile fiber uses, including non-cancer harms -- and is already drawing cautious praise from one of the environmental groups that sued to force the second evaluation.

The agency on Dec. 29 released its draft scope for the Toxic Substances Control Act (TSCA) evaluation, opening a public comment period set to run through Feb. 14.

It includes not only a summary of the asbestos types and uses EPA intends to evaluate, but also possible health risks, exposure pathways and susceptible populations it will consider as it gauges likely risks from the fibers, and appears to cast a wider net for those than the Trump-era "part 1" evaluation.

"For Part 2 of the Risk Evaluation for Asbestos, EPA plans to evaluate the epidemiological literature examining exposure to asbestos and certain cancers and non-cancer effects," EPA explains in the scope document.

It continues that the risk analysis will consider potential damage to most body tissues as well as "certain cancers," based on a wide range of toxicity tests and modeling methods.

That could reflect a significant change in how the agency approaches asbestos, as the "part 1" chrysotile evaluation was widely criticized by EPA science advisors, environmentalists, asbestos victims' groups and Democrats for excluding not only a range of asbestos fiber types and uses, but also numerous health effects.

The part 1 assessment considered only mortality rates from lung cancer and mesothelioma, setting aside other cancers, like ovarian, non-cancer diseases, and any incidences of asbestos-linked disease that could not be linked to mortality.

Environmentalists that criticized the part 1 evaluation are already praising the draft scope as a first step toward a more comprehensive review.

EPA "has taken a critical step in fulfilling its long-delayed obligation to evaluate the risks of legacy asbestos under [TSCA]. The Part 2 risk evaluation will finally provide a robust and comprehensive evaluation of legacy asbestos that can be found in millions of homes, schools, and workplaces," Linda Reinstein, co-founder and president of the Asbestos Disease Awareness Organization (ADAO), said in a Dec. 29 statement.

ADAO is part of the coalition of groups that sued EPA to force the part 2 evaluation, and ultimately secured a pair of court settlements that set a Dec. 1, 2024, deadline for final action on the review as well as milestones in the process and minimum requirements for the proposed scope such as considering "all environmental pathways" of human exposure to asbestos.

The draft scope also echoes the settlements' focus on asbestos impurities in other materials, particularly talc and vermiculite, a once-common building material often contaminated with the so-called Libby amphibole variant of asbestos, as signaled in a Dec. 28 Federal Register notice that announced its release.

ADAO's statement praised the breadth of EPA's proposed scope. "We are proud to have played a part in ensuring the risk evaluation is comprehensive. Evaluating the risks of legacy asbestos is a critical priority, but we also need to address the ongoing risk of asbestos and asbestos-containing products that continue to be imported into the US," Reinstein said, before reiterating her group's call for Congress to ban importation and use of asbestos.

"While EPA continues its work, Congress can and should put an end to the importation and use of asbestos in the United States with an unambiguous ban of asbestos."

Susceptible Populations

The scoping document also lays out the potentially exposed or susceptible subpopulations (PESS) that it will consider as part of the evaluation. Though PESS analysis is required by TSCA, the Dec. 29 draft again indicates a broader approach there than the Trump EPA used.

"EPA plans to consider the following groups as PESS: [...]

EPA Grants Petition to Study The Effects of PFAS on Humans and the Environment

David Collins, Law Street Media

https://lawstreetmedia.com/news/agriculture/epa-grants-petition-to-study-the-effects-of-pfas-on-humans-and-the-environment/

On Tuesday, the Environmental Protection Agency (EPA) granted a petition to initiate the testing of human health and ecological hazards posed by polyfluoroakyl substances (PFAS). This petition was brought by the Center for Environmental Health, Cape Fear River Watch, Clean Cape Fear, Democracy Green, Toxic Free NC, and the NC Black Alliance wanted to make companies test this potentially hazardous substance.

According to the EPA's website, PFAS exposure "may be linked to harmful health effects in humans and animals," which may be a cause for concern as it is found in an abundance of household products and is in the water, air and soil. This renewed interest in analyzing these substances comes after an initiative was started by the Biden-Harris Administration to understand PFAS and protect American citizens from its potential risks. In order to properly analyze the effects of these substances, the EPA will "require PFAS manufacturers to provide the agency with toxicity data and information on categories of PFAS." The EPA will exercise its authority under the Toxic Substances Control Act Section 4 in order to "require recipients of test orders to conduct and fund the studies."

While this petition was previously denied under the Trump Administration, it was reconsidered and approved in September 2021, and the National PFAS Testing Strategy was announced in October. This plan "identifies priority substances for the first of several described phases of an iterative testing approach based on grouping of chemicals by chemistry features and available toxicity data," in order to better understand these substances.

By granting this petition, the EPA will exercise their authority in order to conduct test studies on the lesser known varieties of PFAS, learn more about how they behave in common mixtures, conduct human trials and explore the correct analytical procedures to do so. The EPA will continue to address the spread of PFAS contamination and their actions to stop it in their PFAS Strategic Roadmap.

EPA to require Sterigenics to self-report toxic emissions

Brian Eason, The Atlanta Journal-Constitution https://www.ajc.com/news/atlanta-news/epa-to-require-sterigenics-to-self-report-toxic-emissions/BKADQGC2RBELLD562XINLMHLS4/

A Cobb County medical sterilization facility will have to self-report its emissions of a cancer-causing gas to a federal toxin database under new requirements announced this week by the U.S. Environmental Protection Agency.

The plant, operated by Sterigenics, has sterilized medical equipment since the 1970s using ethylene oxide, an odorless gas regulated by the federal government.

The EPA announced the new rules in a Dec. 27 press release, the latest response to the growing public backlash over the facility. In 2016, the EPA determined that the chemical is a more potent carcinogen than previously acknowledged, and the plant near Smyrna was subsequently flagged in a federal report mapping areas with elevated cancer risks.

The new mandate applies to 29 sterilization facilities across the U.S., including eight owned by Sterigenics, that will have to begin tracking their emissions in January 2022 for their first report in 2023. In documents detailing its decision, the EPA wrote that more than 200,000 people live within a five-mile radius of the Cobb facility, including 12,092 children under age 5. There are 50 schools in that radius, as well.

The EPA has long required other facilities that handle more than 10,000 pounds of ethylene oxide to report their emissions to a federal database, known as the Toxics Release Inventory, which tracks pollutants that are released into the air and water. BD, which operates facilities in Covington and Madison, already reports to the database.

Sterigenics did so, too — until it stopped in 2017.

The EPA's website says the company was not required to report its emissions before now because of a technicality. When Congress created the toxin database in 1987, only companies officially classified as manufacturers were required to report. So even though Sterigenics has handled as much as 40 times the reporting threshold in years past, it was exempt from reporting because its facilities are classified as "support services."

BD is classified as a manufacturer because it also manufactures medical equipment.

Sterigenics told the EPA it was willing to comply with the reporting requirements, noting that it has provided similar information to the EPA and the state Environmental Protection Division in the past, according to EPA documents. The EPD is reviewing whether to require additional reporting of its own, through Sterigenics' air permit.

A Sterigenics spokesman did not immediately return a call seeking comment. The company insists its operations are safe, and says that recent upgrades to its facilities capture more than 99.99% of the ethylene oxide used.

Overnight Energy & Environment — Activists pan EPA chemical testing move

Rachel Frazin and Matt Budryk, The Hill

https://thehill.com/policy/energy-environment/overnights/587674-energy-environment

Let's jump in.

Advocates unhappy with PFAS testing move

It also said that these chemicals are similar to 14 others from the petition and that it will test for four chemicals that are not part of the groups' request, but that are similar to nine of the chemicals.

The EPA argued that in doing this, it's covering 30 of the 54 chemicals from the petition.

The big picture: The move is one of the Biden administration's first concrete indications of the approach it will take to a class of chemicals called PFAS after it announced a plan in October to tackle them.

Certain types of PFAS, or perfluoroalkyl and polyfluoroalkyl substances, have been linked to health issues including kidney and testicular cancer.

The Trump administration initially denied the petition.

The complaint: Lawyer Bob Sussman, who represents the environmental groups, said the requirements are not enough, noting that only seven of the chemicals will actually be studied.

"EPA says they're granting the petition. I think if they denied the petition we would basically be getting the same thing ... 90-plus percent of what we asked for we're not getting," said Sussman, who was a high-ranking EPA official during the Obama and Clinton administrations.

The tests outlined in the petition will include animal studies, but Sussman said he'd specifically like to see epidemiological studies on people who live in Eastern North Carolina.

But the EPA calls it an important step. "By taking action on this petition, EPA will have a better understanding of the risks from PFAS pollution so we can do more to protect people. This data will also help us identify the sources of pollution so we can hold those accountable for endangering the public," said a statement from EPA administrator Michael Regan. "EPA is fully committed to addressing this longstanding pollution challenge, and today we take another critical step forward to protect the water, air, and land we all depend on."

Read more about the agency's action here.

Bayer's Registration of Roundup Fails to Save It From Trials (1)

Martina Barash, Bloomberg Law

https://bnanews.bna.com/class-action/bayers-epa-registration-of-roundup-fails-to-save-it-from-trials

The EPA's pesticide registration procedures aren't safety standards that protect an applicant like Monsanto Co. or its successor Bayer AG from liability under a particular provision of Texas law, a federal court in California said in advance of six Roundup cancer trials.

A different provision of the Texas product liability statute—relating to premarket approval requirements rather than standards—makes that reading untenable, because it more closely describes the Environmental Protection Agency's pesticide registration process, Judge Vince Chhabria said Tuesday for the U.S. District Court for the Northern District of California.

Chhabria oversees consolidated federal Roundup litigation, where eight cases are heading toward trial. The U.S. Supreme Court recently asked for the Biden administration's input as it mulls whether to review a Ninth Circuit decision affirming a \$25 million judgment for a property owner with non-Hodgkin lymphoma. High-profile Roundup litigation is also playing out in California state court.

Six of the plaintiffs in the current wave assert claims under Texas law. Bayer asked the court to presume that companies that comply "with mandatory safety standards or regulations adopted and promulgated by the federal government, or an agency of the federal government" aren't liable under Section (a) of the Texas Product Liability Act.

Bayer "appears to assume that the EPA registration and re-registration processes qualify as 'mandatory safety standards or regulations' within the meaning of the TPLA," Chhabria said.

But that doesn't square with Section (c) of the law, he said. That provision offers a presumption of no liability for companies that comply with the federal government's "procedures and requirements with respect to premarket licensing or approval," where the government ultimately approves the product, Chhabria said. The company's reading of Section (a) would make Section (c) meaningless, he said.

"While Monsanto may have been able to establish that it was entitled to a presumption of no liability under section (c), it does not make that argument in its briefs and instead relies solely on section (a)," he said.

A Bayer spokesperson said in a statement: "While we have great sympathy for the plaintiffs and their families, we are confident that Roundup was not the cause of their illnesses, based on an extensive body of science and the consensus of leading health regulators that find these products can be used safely as directed and are not carcinogenic."

The Miller Firm LLC, Jones & Odom LLP, and Winchell & Joseph LLC are among the attorneys representing the plaintiffs.

Wilkinson Stekloff LLP, Hollingsworth LLP, Covington & Burling LLP, and Bryan Cave Leighton Paisner LLP submitted the brief for Bayer.

The case is In re Roundup Prods. Liab. Litig., 2021 BL 493140, N.D. Cal., No. 3:16-md-02741, 12/28/21.

(Adds Bayer statement in eighth paragraph to story originally published Dec. 29.)

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Draft Revision to Risk Determination for HBCD Retains Finding of Unreasonable Risk of Injury

N/A, Bergeson & Campbell Blogs

https://www.lawbc.com/regulatory-developments/entry/draft-revision-to-risk-determination-for-hbcd-retains-finding-of-unreasonab

On December 29, 2021, the U.S. Environmental Protection Agency (EPA) announced the availability of a draft revision to the risk determination for the cyclic aliphatic bromide cluster (HBCD) risk evaluation issued under the Toxic Substances Control Act (TSCA). 86 Fed. Reg. 74082. EPA is reconsidering two key aspects of the risk determinations for HBCD. First, EPA proposes that the appropriate approach to these determinations under TSCA and implementing regulations is to make an unreasonable risk determination for HBCD as a whole chemical substance, rather than making unreasonable risk determinations separately on each individual condition of use (COU) evaluated in the risk evaluation. Second, EPA proposes that the risk determination should be explicit that it does not rely on assumptions regarding the use of personal protective equipment (PPE) in making the unreasonable risk determination under TSCA Section 6; rather, the use of PPE would be considered during risk management. EPA "finds that HBCD, as a whole chemical substance, presents an unreasonable risk of injury to health and the environment when evaluated under its conditions of use." Comments are due by February 14, 2022.

Background

As reported in our July 1, 2021, memorandum, on June 30, 2021, EPA announced plans to revise specific aspects of the first ten risk evaluations issued under TSCA to ensure that the risk evaluations appropriately identify unreasonable risks and thereby help ensure the protection of human health and the environment. The policy changes include:

Whole Chemical Approach: Under the previous Administration, EPA made separate unreasonable risk determinations for every COU of a chemical. For the first ten chemicals evaluated under TSCA and for any similar chemical that presents significant risks across many uses, EPA will assess and analyze each COU but then make a determination of unreasonable risk just once for the whole chemical when it is clear the majority of the COUs warrant one determination; and

Use of PPE: In the final risk evaluations for the first ten chemicals, the previous Administration generally

assumed that workers were always provided, and used, PPE appropriately. EPA states that data on violations of PPE use suggest that assumptions that PPE is always provided to workers, and worn properly, are not justified, however. EPA is therefore revisiting the assumption that PPE is always used in occupational settings when making risk determinations for a chemical. Instead, EPA plans to consider information on use of PPE, or other ways industry protects its workers, as a potential way to address unreasonable risk during the risk management process.

Draft Revision to the Risk Determination for the Risk Evaluation for HBCD

EPA developed the draft revision following a review of the first ten risk evaluations, and the draft revision reflects EPA's announced policy changes. EPA "finds that HBCD, as a whole chemical substance, presents an unreasonable risk of injury to health and the environment when evaluated under its conditions of use." According to the Federal Register notice, the draft revision supersedes the COU-specific no unreasonable risk determinations in the September 2020 HBCD risk evaluation (and withdraws the associated order) and makes a revised determination of unreasonable risk for HBCD as a whole chemical substance. EPA states that the draft revised risk determination "does not reflect an assumption that workers always appropriately wear" PPE.

EPA states that it is specifically seeking public comment on the draft revision to the risk determination where EPA intends to determine if HBCD, as a whole chemical substance, presents an unreasonable risk of injury to health and the environment when evaluated under its COUs. According to EPA, this whole chemical approach to determining unreasonable risk to health is permissible under EPA's statutory obligations under TSCA Section 6(b)(4) and the implementing regulations and [...]

EPA Grants TSCA Section 21 Petition to Order Testing on Human Health Hazards of PFAS

Lynn L. Bergeson and Carla N. Hutton, Bergeson & Campbell Blogs http://www.tscablog.com/entry/epa-grants-tsca-section-21-petition-to-order-testing-on-human-health-hazard

The U.S. Environmental Protection Agency (EPA) announced on December 28, 2021, it is granting a petition from six North Carolina public health and environmental justice organizations filed under Section 21 of the Toxic Substances Control Act (TSCA) to compel companies to conduct testing of certain per- and polyfluoroalkyl substances (PFAS). The previous Administration denied the petition on January 22, 2021. 86 Fed. Reg. 6602. The petition sought issuance of a rule or order under TSCA Section 4 compelling The Chemours Company to fund and carry out this testing under the direction of a panel of independent scientists. The petitioners requested that EPA reconsider its denial in March 2021, which EPA agreed to do in September 2021, in light of the change in Administration and attendant change in policy priorities concerning PFAS. As reported in our October 19, 2021, memorandum, EPA published a National PFAS Testing Strategy (Testing Strategy) that identifies priority substances for the first of several described phases of an iterative testing approach based on grouping of chemicals by chemistry features and available toxicity data. EPA states that these substances include many of the chemicals identified in the petition, as well as additional PFAS that will inform a wider universe of categories of PFAS where key data are lacking. For example, according to EPA, the first phase of testing on 24 PFAS is expected to provide data that can be extrapolated to 2,950 PFAS that belong to the same categories as the 24 individual substances.

EPA states that it has granted the petition and will use its TSCA Section 4 order authority to require PFAS manufacturers to conduct and fund the following studies that will provide toxicity data and information on categories of PFAS:

Near-Term Testing Covers 30 of 54 Petition Chemicals -- Under the Testing Strategy, EPA's first test orders for 24 categories of PFAS about which the least is known will provide human health hazard data that cover 30 of the 54 petition chemicals;

Subsequent Testing May Cover Nine of 54 Petition Chemicals -- An additional nine PFAS identified in the petition belong to one other category included in the Testing Strategy. EPA is conducting more in-depth analyses of the sufficiency of the existing data, which will inform later phases of testing;

Remaining 15 of 54 Petition Chemicals -- According to EPA, 15 chemicals identified in the petition do not fit the definition of PFAS used in developing the Testing Strategy. EPA has determined that there are robust data on some of them available to it. EPA is conducting more in-depth analyses of the existing data, which will inform later phases of testing;

Mixtures Studies -- EPA will address PFAS mixtures by using the toxicity of the individual substances to predict the toxicity of the mixture, an approach which is consistent with the current state-of-science on PFAS. EPA is proceeding with development and peer review of these methods as specifically applied to PFAS; Human Studies -- EPA is contributing to and reviewing numerous existing ongoing human studies, including studies on potentially exposed workers and communities in North Carolina, and is evaluating how to advance and expand on these efforts further. These include studies of health outcomes for people in communities impacted by industrial PFAS releases, as well studies that explore the connection between chronic health outcomes and PFAS exposures in North Carolina; and

Analytical Standards -- EPA does not believe it is appropriate to require the development or submission of analytical standards with the initial test orders that will be issued under the Testing Strategy and lacks the ability to order the submission of all analytical standards in the manner requested. Nonetheless, EPA has requested comment on whether to require the submission of existing analytical methods for PFAS under a separate rulemaking that the Agency expects to issue in final next year. [...]

BREAKING: Biden EPA Fails to Protect North Carolina Communities and Hold Chemours Accountable for Massive PFAS Pollution

Emily DiFrisco, Center for Environmental Health

https://ceh.org/latest/press-releases/breaking-biden-epa-fails-to-protect-north-carolina-communities-and-hold-chemours-accountable-for-massive-pfas-pollution/

FOR IMMEDIATE RELEASE – Dec. 29, 2021

Biden EPA Fails to Protect North Carolina Communities and Hold Chemours Accountable for Massive PFAS Pollution

While Claiming to "Grant" their Petition, EPA Uses Smoke and Mirrors Strategy to Camouflage Failure to Require Essential Studies to Understand the Health Impacts of Decades of PFAS Pollution

WILMINGTON, NORTH CAROLINA – Six North Carolina community and environmental justice groups are "deeply disappointed" by EPA's "inadequate" response yesterday to their petition asking the Agency to require Chemours to conduct a critical epidemiological study and health toxicity testing on 54 per- and polyfluoroalkyl substances (PFAS) that are putting hundreds of thousands of North Carolina residents at risk. Petitioners said they are considering all options, including litigation, to challenge EPA's decision.

The six groups are: Center for Environmental Health, Cape Fear River Watch, Clean Cape Fear, Democracy Green, the NC Black Alliance, and Toxic Free NC. The testing petition, filed October 14, 2020, asked EPA to require Chemours to fund a comprehensive research program addressing the concerns of Cape Fear communities who have been exposed for decades to numerous PFAS in their drinking water, air, food, and soil because of pollution from the Chemours facility in Fayetteville. Several of these compounds are also present in the blood of North Carolina residents, yet little or no government-backed health data are currently available that would shed light on the harm these communities, and others like them, across the U.S. have suffered.

EPA's petition response did not announce any new studies on the 54 PFAS. It said it would require limited

testing on 7 of the 54 PFAS, but this testing had previously been announced in October under EPA's general PFAS testing strategy. In declining to require testing on additional PFAS produced by Chemours, EPA claimed it could determine their health effects by extrapolating from studies it plans to require on 24 "representative" substances under its testing strategy. This highly theoretical and unproven approach, which is based on complex computational models, rejects the recommendations of petitioners, more than 120 public health organizations, and dozens of leading scientists that EPA should focus testing on those PFAS that directly threaten human health.

Simply put, EPA has had over a year to review the many letters and submissions of petitioners explaining the concerns of North Carolina communities but has completely missed the entire purpose of the petition—to address the public health needs of a severely contaminated community. Instead, the EPA asserts it is "granting" the petition but in fact is deferring action on petitioners' testing requests indefinitely.

EPA refused to commit to requiring the studies that are most important in understanding the human health effects of long-term PFAS contamination on North Carolina communities. In fact, EPA provided no assurance that it would require cancer studies on any PFAS; refused to require an epidemiological study on the exposed human population; and declined to require testing of any of the mixtures of PFAS found in drinking water and human blood.

In announcing EPA's PFAS Roadmap in Raleigh, North Carolina on October 18, Administrator Michael Regan acknowledged the "decades of unchecked devastation" that Cape Fear communities have suffered and emphasized the unexplained and serious health disorders residents are battling. He promised to support communities "[n]ot with empty rhetoric, but with real solutions and with a pledge to hold polluters accountable."

Unfortunately, EPA's petition response does not honor these commitments. It does not "hold polluters accountable" and does not "put people first."

Dana Sargent of Cape Fear River Watch said, "As the director of an environmental nonprofit who believed in and trusted the folks of this EPA to do the right thing, I am furious; as a [...]

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